Position

The lists will not solve the problem with the re-export

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An electronic health system is needed - only this way, the control will be objective - considers the Bulgarian Association of Medicines Parallel Trade Development

The Government published its Management Program by 2020. Part of its health priorities are related to limiting the shortage of drugs generated by parallel trade. The measures will be laid down in the Law on Medicinal Products in Human Medicine. Clinica.bg has already presented the ideas of health authorities for changes. We asked the Bulgarian Association of Medicines Parallel Trade Development (BAMPTD) how appropriate they are. Three of the largest distributors in this segment are members of BAMPTD. The latter is also a part of the European Association of Parallel Trade (EAEPC), where there are about 80 wholesalers.

Whatever lists are proposed for regulation of parallel trade, they would not work and patients will continue to complain, with and without grounds, of lack of medicines. It is not a secret that sometimes false signals of a shortage of medicines are generated, which is a problem of logistics or attempts to limit buying out them from pharmacies. When a similar attempt is made, the reaction is "you do not give me and you break my interest, but I have the means and the way to influence you". Therefore, the ultimate effect of the proposed changes is that wholesalers who work legally will suffer, because the quantities disappear from the network not at distribution level but at pharmacy level.

In order to avoid problems, the state must do its job

in the field of control. This can only be done by introducing an electronic system, which allows you to see what happens within the system. This is the only objective and workable option of control. In all other cases, the interests only of legitimate wholesalers who currently are complying with the legal rules are affected. Proof of this is the membership in EAEPC, where rigorous mechanisms exist to control and guarantee patient safety.

The rules were introduced in 2007 yet, because the number of cases of counterfeit medicines at that time has increased. In response to this problem, the European Association created two tools - an Early Warning Platform and Rules for Good Distribution Practice that each of its members shall respect.

The Rules require that every Association member

must undergo an external audit as to demonstrate the ability of the company to perform the business and protect itself from purchase of falsified medicines. If a distributor has passed the audit, the process of structuring and licensing, this is a proof that he has implemented a system, preventing him from supplying medications from occasional suppliers. Audits are mandatory for each new member of the Association, then they are performed on a regular basis. The three Bulgarian companies that are members of the European Association have already gone through such an inspection. In addition, their European partners themselves check them to make sure that they will not have problems with the medicines they buy.

The Early Warning Platform is the other precaution

that its members observe. In case the wholesaler receives any deviation from the usual information about a medicine - packaging, prices, delivery conditions, he sends a signal to the European Association that immediately checks it. This is done in cooperation with the Regulators and manufacturers. Decision on releasing the medicines in the supply chain is taken only after completion of the inspection. Thus, again patient safety is reassured.